

### **Remarks**

Claims 20, 21, 24, 28-30, 32-39, and 47-49 and 51-55 are currently pending in the application, including independent claims 20, 30, and 48 and withdrawn claims 30, 32-39 and 47. For instance, independent claim 20 is directed to an implantable fixed tissue comprising cross-linked elastin. More specifically, the elastin of the implantable fixed tissue is cross-linked with a phenolic tannin cross-linking agent. The implantable fixed tissue includes an elastin content of at least about 30% by weight of the implantable fixed tissue.

In the Office Action, claims 20, 21 and 48 were rejected under 35 U.S.C. §112, first paragraph. Merely for purposes of furthering prosecution of the captioned application, the phrases, "including a residue of the phenolic tannin cross-linking agent bound to and cross-linking the elastin of the fixed tissue," and, "including a residue of an aldehyde cross-linking agent bound to and cross-linking the cross-linked collagen of the fixed tissue," have been removed from the claims. Applicant maintains, however, that these phrases are fully supported by the specification as filed, and these amendments have not been made for any reasons related to patentability.

In the Office Action, independent claims 20 and 48 were rejected under 35 U.S.C. §103(a) as being unpatentable over Tasiaux, et al. (International Publication No. WO 01/21228) in view of Nguyen-Thien-Nhon (U.S. Patent No. 6,001,126).

Applicants respectfully submit that independent claims 20 and 48 patentably define over the cited references for at least the reason that even if combined as suggested, the combined references still fail to teach limitations of the claims. For instance, neither Tasiaux, et al. nor Nguyen-Thien-Nhon disclose or suggest a fixed tissue including an elastin content of at least about 30% by weight of the implantable fixed tissue.

Tasiaux, et al. relates to cardiac valves made from a biological or biocompatible tissue having a resistance to calcification. Specifically, an appropriate biological tissue may be a tissue removed from the heart of an animal, from the aortic valve of an animal, or from the pericardium of an animal (p. 2, ll. 25-28). These tissues, however, are not high elastin content tissues as are found in the pending claims. For instance,

and as described in the captioned application (see, e.g., paragraphs [0050], [0053], and Figure 4), pericardial tissue contains only about 2% by weight elastin, and aortic cusps contain less than 10% elastin. In contrast, the fixed implantable tissue of the pending claims include an elastin content of at least about 30% by weight.

Similarly, the aortic bioprosthesis of Nguyen-Thien-Nhon cannot be said to include a high elastin content as is found in the pending claims. The stentless heart valve of Nguyen-Thien-Nhon is formed of a preserved segment of mammalian aorta that includes an inflow rim or inflow end IE, an outflow rim or outflow end OE, the aortic valve leaflets therewithin, and segments of the right and left main coronary arteries extending from the aortic segment (col. 4, ll. 18-27). At least some portions of this valve, for instance the aortic valve leaflets within the aortic segment, are extremely low in elastin content, as discussed above. Accordingly, while portions of the bioprosthesis of Nguyen-Thien-Nhon may have a high elastin content, for instance aortic wall portions, the implantable fixed tissue as a whole cannot be assumed to have a similar high elastin content.

For at least these reasons, Applicants respectfully submit that independent claims 20 and 48 patentably define over the cited references and request withdrawal of the rejection and allowance of the claims.

Applicants also respectfully submit that for at least the reasons indicated above relating to corresponding independent claims 20 and 48, the pending dependent claims patentably define over the references cited. However, Applicants also note that the patentability of the dependent claims certainly does not hinge on the patentability of independent claims. In particular, it is believed that some or all of these claims may possess features that are independently patentable, regardless of the patentability of the independent claims.

As a final matter, Applicants respectfully request rejoinder of withdrawn claims 30, 32-39 and 47 to the pending application. The claims are related as subcombination/combination claims. Such claims require two-way distinctness for maintenance of a restriction requirement. Specifically, the inventions are distinct if it can be shown that a combination as claimed (A) does not require the particulars of the

subcombination as claimed for patentability and (B) the subcombination can be shown to have utility either by itself or in another materially different combination (MPEP §806.05(c)). In the present instance, Applicants submit that the combination as claimed in independent claim 30 requires the implantable fixed tissue as claimed in the subcombination of independent claim 20. Accordingly, the two-way distinctness requirement has not been met, and Applicants request rejoinder of the claims.


It is believed that the present application is in complete condition for allowance and favorable action is therefore requested. Examiner Khan is invited and encouraged to telephone the undersigned at her convenience should there be any questions with regard to this application.

Please charge any additional fees required by this Amendment to Deposit Account No. 04-1403.

Respectfully submitted,  
DORITY & MANNING, P.A.

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